

### REMARKS

Claims 1 – 11 are pending in this application. The Office Action has rejected, under 35 USC § 103, claims 1 – 4, 6 – 9 and 11 over Cade et al. (WO 97/04755) in view of XP-002143507. The Office Action also rejected, under 35 USC § 103, claims 1 – 7 and 9 – 11 over Cade in view of Yajima (US Patent 4,525,306).

By this Amendment, claims 12 – 14 are added. Reconsideration in view of the above amendments and the following remarks is respectfully requested.

### **Information Disclosure Statement**

The Office Action indicated that reference EP 0240581, which was cited in Applicant's Information Disclosure Statement filed January 12, 2001, has not been considered because it was not translated and it did not contain an English abstract.

Applicant submits herewith a Supplemental Information Disclosure Statement including EP 0240581 B1 and an English abstract.

### **Claim Rejections – Cade and XP**

The Office Action rejects, under 35 USC § 103, claims 1 – 4, 6 – 9 and 11 over Cade et al. (WO 97/04755, hereinafter “Cade”) in view of XP-002143507 (hereinafter “XP”).

These rejections are respectfully traversed.

Applicant asserts that neither Cade nor XP discloses or suggests “a gelatine capsule being xylose-hardened to an extent sufficient to inhibit peroxidation of polyunsaturated fatty acids” as recited in independent claim 1 and similarly recited in independent claim 11. Further, Applicant asserts that there is no motivation to combine Cade with XP, and that even in combination the cited references would not have provided a reasonable expectation of success of producing the claimed invention.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the reference or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings to produce the claimed invention. Second, there must be a reasonable

expectation of success. Finally, the prior art references, when combined, must teach or suggest all of the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure (*In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991)). The prior art must suggest the desirability of the claimed invention (MPEP § 2143.01).

XP discloses a **lipid formulation** for treating inflammatory **bowel disease**. The composition may include fats and oils containing omega-3-polyenoic fatty acid and an extract of leaves of perilla. The composition may be charged into a gelatin soft capsule. See Abstract. The Office Action admits that XP does not disclose the composition of the gelatin capsule.

Cade discloses hard gelatin capsules with reduced water permeability. The objective of Cade is to **reduce the risk of destabilization** of hard gelatin capsule content **due to humidity**, and Cade discusses at length the problems of moisture associated with gelatin capsules (see page 1, line 9 – page 3, line 30). Water transport and hygroscopicity are the only problems that Cade discusses or is concerned with solving.

Cade discloses that water transport may be reduced by laminating a gelatin capsule with a polymer layer, or by adding at least one polyol to the gelatin formulation during production (see page 4, lines 1 – 7). Suitable polyols to be used during gelatin production include sugars, sugar alcohols and other sugar substitutes, as well as polyvinyl alcohol and structural analogues thereof (see page 6, lines 15 – 25).

Thus, Cade teaches adding a polyol to the gelatin in order to reduce water permeability.

Neither Cade nor XP makes any disclosure as to the problem of **peroxidation**, or the **prevention of peroxidation** of polyunsaturated fatty acids within a gelatin capsule.

Therefore, the cited references do not teach or suggest all of the limitations of independent claims 1 or 11.

Additionally, the Examiner has provided absolutely no motivation to combine the Cade gelatin capsule with the XP composition, as the Examiner has not cited any reference that teaches a risk of destabilization of polyunsaturated fatty acids due to humidity.

Even assuming for the sake of argument that there is motivation to combine Cade with XP, the combination would teach a composition of omega-3-polyenoic fatty acid and an extract

of leaves of perilla within a gelatin capsule that has been treated with a polyol to reduce water permeability. A person of ordinary skill in the art attempting to reduce peroxidation of polyunsaturated fatty acids within a gelatin capsule would not be lead to the combination of the Cade gelatin capsule with the XP composition, as neither reference even mentions the peroxidation of fats.

Further, the addition of xylose to the gelatin capsule does not necessarily reduce water permeability. Applicant's own tests show that in at least one embodiment of a xylose treated capsule sufficient to inhibit peroxidation of polyunsaturated fatty acids, when stored for 6 months at 30°C temperature and 60% humidity the capsule may become dark and begin to lose its shape due to moisture. For this reason, the Applicant's commercial product is labeled, "Keep in a dry place." Thus, the gelatin capsule as claimed herein does not necessarily inhibit moisture permeation.

The Examiner argues that Cade's disclosure of chemical degradation of the substance within the capsule due to moisture reads on the problem of peroxidation of fatty acids. The Examiner also argues that prevention of the presence of oxygen is implicit in the prevention of moisture penetration in the Cade capsule (see page 4 of Office Action).

Applicant respectfully disagrees with both of the Examiner's contentions. As to chemical degradation, Cade states, "**Moisture take-up** by fills from capsules or more frequently from the environment by permeation may affect the properties of powder fills: they may agglomerate or, more seriously, degrade chemically for example by hydrolysis" (page 2, lines 16 – 20 (emphasis added)). Thus, the teaching in Cade of chemical degradation is limited to degradation caused by moisture. Cade does not disclose or suggest any inhibition of peroxidation.

Applicant asserts that reading a problem of peroxidation into the Cade disclosure constitutes an impermissible use of hindsight based from Applicant's disclosure. Obviousness cannot be established by hindsight combination to produce the claimed invention (see *In re Gorman*, 18 USPQ2d 1885 (Fed.Cir.1991)). It is the prior art itself, and not the applicant's achievement, that must establish the obviousness of the combination.

As to the Examiner's argument that reduced oxygen permeability is implicit in the Cade capsule, Applicant asserts that a material with high resistance to water permeability does not

necessarily have an inherent resistance to oxygen permeability. In the more specialized field of barrier polymers:

“Some polymers show excellent gas barrier properties but poor water barrier rates...; and others are poor gas barriers but good water barriers....”

Steingiser et al. “Barrier Polymers.” *Kirk-Othmer Concise Encyclopedia of Chemical Technology*. New York: John Wiley & Sons, Inc., 1985. A copy of this document is attached hereto. Consequently, the Examiner has shown no reasonable basis upon which a skilled person, seeking to solve a peroxidation problem, could expect to succeed using Cade’s capsules.

Further, consideration of an inherent quality is relevant only to anticipation, not obviousness (*Jones v. Hardy*, 230 USPQ 1021 (Fed. Cir. 1984)).

Therefore, Applicant respectfully submits that independent claims 1 and 11 are not made obvious by Cade in view of XP. Claims 2 – 4 and 6 – 9 depend from claim 1 and are also not made obvious. Applicant requests withdrawal of the rejections.

#### **Claim Rejections – Cade and Yajima**

The Office Action also rejects, under 35 USC § 103, claims 1 – 7 and 9 – 11 over Cade in view of Yajima (US Patent 4,525,306).

These rejections are respectfully traversed.

Applicant asserts that neither Cade nor Yajima discloses or suggests “a gelatine capsule being xylose-hardened to an extent sufficient to inhibit peroxidation of polyunsaturated fatty acids” as recited in independent claim 1 and similarly recited in independent claim 11. Further, Applicant asserts that the Examiner has provided no motivation to combine Cade and Yajima, as Yajima teaches away from the claimed invention.

As discussed above, Cade discloses hard gelatin capsules with reduced water permeability to reduce the **risk of destabilization of contents due to humidity**.

Yajima discloses soft capsules containing oils and fats, and the prevention of oxidation of oils and fats by the **addition of an antioxidant**, such as butylated hydroxyanisole, butylated hydroxytoulene and tocopherol (see column 1, lines 6 – 20), or a component derived from herb spices (see column 2, lines 53 – 66). Thus, Yajima teaches the reduction of oxidation of oils and

fats by the use of chemical antioxidant preservatives mixed into the oil and fat composition contained within a soft gelatin capsule.

One of ordinary skill in the art viewing Yajima and Cade would not be motivated to use the capsule of Cade with the composition of Yajima for the purpose of oxidation prevention, as Yajima already solves the oxidation problem. Yajima teaches a method of inhibiting peroxidation utilizing antioxidant additives. Thus, Yajima teaches away from the claimed invention. Further, even if the references were combined, there is no teaching that the Cade capsule would have any benefit in the prevention of oxidation.

Applicant's own disclosure discusses the use of antioxidants as a prior art method of reducing oxidation (page 1, lines 6 – 11). Further, the final sentence of Applicant's disclosure on page 5 states that the finished xylose-hardened capsule inhibits the peroxidation of fatty acids so that the addition of antioxidants is unnecessary.

Similarly to the Examiner's previous rejection over Cade in view of XP, the Examiner argues that Cade's disclosure of chemical degradation due to moisture reads on the problem of peroxidation of fatty acids, and that reduced oxygen permeability is implicit in the Cade capsule.

Applicant hereby puts forth the arguments used to rebut these contentions in the previous section, and asserts that the Examiner's arguments do not help to present a *prima facie* case of obviousness.

Thus, Cade in view of Yajima does not disclose or suggest a "gelatine capsule being xylose-hardened to an extent sufficient to inhibit peroxidation of polyunsaturated fatty acids" as recited in independent claims 1 and 11.

Therefore, Applicant respectfully submits that independent claims 1 and 11 define patentable subject matter. Claims 2 – 10 depend from independent claim 1 and therefore also define patentable subject matter. Accordingly, Applicants respectfully request the withdrawal of the rejections 35 USC § 103.

FORMALITIES

If an extension of time is required to make this response timely and no separate petition is enclosed, Applicant hereby petitions for an extension of time sufficient to make the response timely. In the event that this response requires the payment of government fees and payment is not enclosed, please charge Deposit Account No. 22-0350.

CONCLUSION

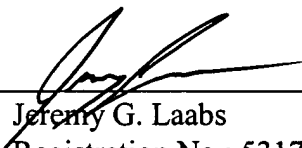
Based on at least the foregoing amendments and remarks, Applicants respectfully submit this application is in condition for allowance. Favorable consideration and prompt allowance of claims 1 - 14 are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in better condition for allowance, the Examiner is invited to contact Applicants' undersigned representative at the telephone number listed below.

Respectfully submitted,

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